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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/206,249	12/07/1998	MIRI SEIBERG	JBP438	5255
7590	05/23/2002			
PHILIP S. JOHNSON, ESQ. JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER	
			MELLER, MICHAEL V	
		ART UNIT	PAPER NUMBER	
		1651		
		DATE MAILED: 05/23/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/206,249	SEIBERG ET AL.
	<b>Examiner</b> Michael V. Meller	<b>Art Unit</b> 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 March 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 23-25,28-41 and 44-58 is/are pending in the application.
- 4a) Of the above claim(s) 23,25,37,39,41 and 48-57 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 24,28-36,38,40,44-47 and 58 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

### ***Election/Restrictions***

The election of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

Claims 24, 28-35, 38, 40 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakl et al. for the reasons of record and for the reasons which follow.

Applicant's comments are noted but they merely show that some people may choose to heat the soybean milk before use but the comments do not negate the fact that Limtrakul et al. clearly does not. The other comments concerning Limtrakul are also not well taken since Limtrakul clearly applies the soybean milk to mouse skin, page 1592, fourth paragraph, and never heats the milk, page 1592, third paragraph.

Claims 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka for the reasons of record and for the reasons which follow.

Applicant's comments merely show that some people may choose to heat the soybean milk before use but does not negate the fact that Kosaka clearly does not. Applicants other comments concerning Kosaka are not well taken since Kosaka clearly contemplates treating skin diseases, col. 2, lines 1-10, and never heats the soybean milk, col. 5, lines 14-17, further Kosaka contemplates suppositories which do contact the skin.

Claims 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62036304 (JP) for the reasons of record and for the reasons which follow.

JP still would contain soybean milk which would inherently have the soybean trypsin inhibitor whether the composition was heated or not.

The declaration by Katherine Martin is noted but JP does show topically applying the same composition as that claimed to a patient. Ms. Martin's comments are noted but the same composition as that claimed is applied in the same way as that claimed. The same results are thus inherently obtained.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA § 102(e)).

Claims 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/110,409 for the reasons of record and for the reasons which follow which has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Patent application Serial Number 09/110,409 is still a pertinent reference since the application claims administration of the same composition to a mammal.

### ***Claim Rejections - 35 USC § 103***

Claims 24, 28-36, 38, 40, 44-47 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with Kosaka or JP 62036304 (JP) for the reasons of record and for the reasons which follow.

The above comments apply here as well concerning these references.

***Double Patenting***

Claims 24, 28-36, 38, 40, 44-47 and 58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of copending Application No. 09/110,409 for the reasons of record and for the reasons which follow. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims have not in fact been patented.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Patent application Serial Number 09/110,409 is still a pertinent reference since the application claims administration of the same composition to a mammal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

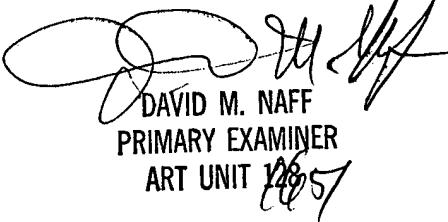
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308-0294 for regular communications and 703-308-0294 for After Final  
communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703-308-  
0196.

MVM  
May 21, 2002



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651